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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,190	04/10/2001	Katsuya Matsuda	MATSUDA 13	4190

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EXAMINER
GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,190	MATSUDA ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-40,42-49 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-40,42-49 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments and Remarks received on June 22, 2004 is acknowledged. Claims **31-40, 42-49, and 53** are pending in this application. Claims 1-30, 41, and 50-52 stand cancelled.

Claim Rejections - 35 USC § 102

The rejection of claims 29-30 and 50-52 under 35 U.S.C. 102(e) as being anticipated by Holmes-Farley et al (6,423,754) is withdrawn in view of the cancellation of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 31-32, 36, 41-43, 49 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) is maintained.

Holmes-Farley et al disclose the method of preparing cross-linked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia. See abstract and column 3, lines 35-50. Suitable forms for administration are tablets, capsules, or powders. Further, the polymer may be administered alone or in combination with a carrier. See column 3, lines 35-60. The polymers are prepared by combining polyallylamine hydrochloride, acetonitrile, and epichlorohydrin, yielding particles in a solution. The solid particles are then dried and passed thorough a 50-mesh screen (approximately 300 microns). See examples on column 6, lines 15-45.

Holmes-Farley et al does not exemplify the tablet formulation.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Holmes-Farley et al and utilize a tablet formulation containing the phosphate-binding polymer. One would be motivated to do so with the expectation of similar results since the prior art clearly teaches that the tablets are suitable form for administering the instant polymers. Therefore, one would be motivated to utilize the dosage form of choice depending on the desired type of administration.

Response to Arguments

Applicant does not argue the instant rejection or the examiner's statement that the specific gravity and properties of the phosphate-binding polymer are inherent. It should be noted that this is based on Holmes-Farley use of solvent mixture of water and acetonitrile and cross-linking polyallyamine with epichlorohydrin in conjunction with applicant's statement that the

instant phosphate-binding polymers have the instant specific gravity due to the utilization of a solvent mixture of water, acetonitrile, and cross-linking polyallyamine with epichlorohydrin.

Therefore, the rejection is maintained.

The rejection of claims 33-40 and 44-48 under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al (6,423,754) in view of Sato et al (5,202,335) is maintained.

Holmes-Farley et al disclose the method of preparing cross-linked phosphate-binding polymers in oral formulations for the treatment of hypercholesterolemia. See abstract and column 3, lines 35-50. Suitable forms for administration are tablets, capsules, or powders. The polymer may be administered alone or in combination with a carrier such as magnesium carbonate, lactose, etc and can be coated to protect the composition from disintegration. See column 3, lines 35-60. The polymers are prepared by combining polyallylamine hydrochloride, acetonitrile, and epichlorohydrin, yielding particles in a solution. The solid particles are then dried and passed thorough a 50-mesh screen (approximately 300 microns). See examples on column 6, lines 15-45.

Holmes-Farley does not specify the instant excipients: crystalline cellulose or HPC.

Sato et al teach succinic compounds for oral administration. Sato teaches that in molding pharmaceutical compositions into tablet formulations, many conventional carriers known in the art may be used. These carriers include lactose, sucrose, microcrystalline cellulose, etc. Sato also teaches the use of conventional disintegrators such as low-substituted HPC. The tablets may be coated with a sugar coating, gelatin coating, enteric coating, and film coating, depending on the

desired effect. See column 8, lines 54-68. Sato teaches various suitable excipients for the composition that are known in the art. See column 9, lines 1-16.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Holmes-Farley et al and Sato et al. One would have been motivated to do so since Sato teaches that instant tablet coat and instantly claimed excipients are conventional in the tabletting art. Further, Sato teaches the functional equivalency of Holmes-Farley's suggested lactose carrier and instant microcrystalline cellulose. Therefore, one would be motivated to substitute one carrier with another with a reasonable expectation of similar result. Additionally, skilled artisan would be motivated to coat the tablet depending on the desired effect of the composition, i.e. a sugar coat for a palatable tablet or a film coat for a smooth, glossy appearance.

Response to Arguments

Applicant argues that the inventors have tested additives of Holmes-Farley US patent 5,496,545 but the tablet did not have sufficient hardness, rapid dispersibility, and the ability to bind the phosphate. Applicant argues that the instant tablets have sufficient hardness since they have an average particle size of no more than 400 microns, instant specific gravity, and a water content of 1-14%. Applicant argues that Holmes-Farley '754 is silent to the hardness of the tablets. Lastly, applicant argues that although Holmes-Farley used the instant solvent mixture to produce a particle with the instant properties, this was done accidentally and patent '754 did not realize that there is a difference in specific gravity between polymers produced with a water/acetonitrile mixed solvent and one produced with water alone.

Applicant's arguments have been fully considered but they are not persuasive. Although the applicant states that Homles-Farley does not teach the hardness of the tablet, the examiner points out this is not a claim limitation; therefore applicant's arguments are based on a feature that is not claimed.

Secondly, it is noted that applicant has not argued the examiners' position of inherency as discussed above nor stated with evidence that Holmes-Farley does not have instant properties. Therefore, the examiner maintains that Holmes-Farley does teach phosphate-binding polymer with the instant properties in the examples in column 6, absent evidence indicating otherwise.

Thirdly, applicant claims that Holmes-Farley has "accidentally" produced the instant phosphate-binding polymer. The examiner points out that regardless of the reasons as to why the prior art has produced the instant phosphate-binding polymer, it is still constitutes art. The prior art does not have to recognize each and every advantage of the claimed product or process, i.e. that there is a difference in specific gravity between polymers produced with a water/acetonitrile mixed solvent and one produced with water alone. Holmes-Farley '754 constitutes prior art since it not only teaches the same phosphate-binding polymer but the process of making the polymer, which is the same as the applicant's. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant argues Sato et al do not cure the deficiencies of US patent '754. Applicant argues that even though Sato teaches the use of the instant additives as conventional, Sato does not teach it in combination with the phosphate-binding polymer.

The examiner's relies on Sato's teaching that the instant additives (microcrystalline cellulose and low-substituted HPC) are conventional excipients for tablet formulations. The examiner does not rely on Sato to teach the phosphate-binding polymer with the instant properties since the primary reference teaches this.

Lastly in regards to applicant's arguments based on unexpected results, the examiner points out that applicant bases unexpectedness on patents and not the prior art that is currently being used to reject the claims, US patent 6,423,754.

Therefore, the rejections are maintained.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

MICHAEL G. HARTLEY
PRIMARY EXAMINER